

Application No.: 09/391,606

4

### REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of four months of the period for response to the Office Action. Our cheque in respect of the prescribed fee is enclosed.

In the Advisory Action, the Examiner indicated that rejection of claims 10 and 11 under 35 USC 112, second paragraph, was considered to be overcome by the amendments made thereto. Withdrawal of the rejection of those claims on this ground is gratefully acknowledged.

The Examiner maintained rejection of claims 1, 2, 4 to 7, 9 to 17, 19 and 20 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention, at the time the application was filed, had possession of the claimed invention.

The Examiner indicated that the claims do not specify a particular nucleotide sequence. In this regard, claim 1 has been limited to nucleotide sequences which encode the MOMP and 76 kDa protein of *Chlamydia pneumoniae*, in accordance with previous claims 2 and 7, which have been deleted. In addition, claim 1 has been amended to recite that the first nucleotide sequence is selected from those having SEQ ID Nos: 12, 13, 14, 15 and 16, in accordance with previous claims 4 and 5, which have been deleted. These sequences are described in the description of Figure 3 and are shown in Figure 3. Further, claim 1 has been amended to recite that the second nucleotide sequence is selected from those having SEQ ID Nos: 1, 2, 3 and 4. These sequences are described in the description of Figure 1 and are shown in Figure 1.

It is submitted that it is clear that applicants were in possession of the invention so limited, since the respective nucleotide sequences are provided in the Figures. Accordingly, it is submitted that claims 1, 2, 4 to 7, 9 to 17, 19 and 20, insofar as they remain in the application and in their amended form, fully comply with

Application No.: 09/391,606

5

the written description requirements of 35 USC 112, first paragraph, and hence the rejection thereof on this ground should be withdrawn.

The Examiner maintained rejection of claims 1, 2, 4 to 7 and 9 to 20 under 35 USC 112, first paragraph, on the basis that the specification, while being enabling for administration of a plasmid encoding the disclosed MOMP and a plasmid encoding the disclosed 76 kDa of *C. pneumoniae* before challenge by *C. pneumoniae* and induction of a protective immune response against sublethal *C. pneumoniae* lung infection in mice, does not reasonably provide enablement for an immunogenic composition comprising a vector encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for the protection of any host, including human, against a particular disease, such as any chlamydial infection.

As noted above, claim 1 has been directed to *C. pneumoniae* sequences defined by SEQ ID Nos. In addition, claim 1 has been limited to plasmid vectors with claims 13 to 17 being consequentially deleted. Further, claim 1 has been amended to delete reference to the immunogenic composition being for *in vivo* administration to a host.

The claims, therefore, have been amended to limit the claims to an immunogenic composition which recites almost all of the Examiner's limitations for enablement. With respect to the Examiner's assertion with respect to the use of the immunogenic composition, it is sufficient for enablement that the defined subject matter have a utility. Applicants' claims are directed to an immunogenic composition and not to a method of gene therapy *in vivo*. The applicants have used vectors pCA76kDa to illustrate that the immunogenic composition can protect mice from *Chlamydia* infection. In addition, the composition could be used for diagnostic purposes or to generate antibodies to the proteins.

Application No.: 09/391,606

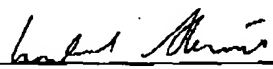
6

Having regard to the amendments made to the claims, it is submitted that claims 1, 2, 4 to 7 and 9 to 20 are fully enabled and hence the rejection thereof under 35 USC 112, first paragraph, on this ground, should be withdrawn.

Entry of this Amendment after Final Action is requested, in that the application thereby is placed in condition for allowance. In the event the Examiner considers one or more ground of rejection to apply, the Amendment nevertheless should be entered, since the claims thereby are placed in better condition for appeal and/or issues for appeal are reduced.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

  
\_\_\_\_\_  
Michael I. Stewart  
Reg. No. 24,973

Toronto, Ontario, Canada,  
(416) 595-1155  
FAX No. (416) 595-1163